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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,960	12/22/2000	Michael Strobel	02581-P0350A	8504

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EXAMINER

RAGONESE, ANDREA M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,960

Applicant(s)

STROBEL ET AL.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-11, 14 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8, 14, 20-22 and 24 is/are rejected.
- 7) ☒ Claim(s) 9-11 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Response to Amendment

1. The Request for Continued Examination (RCE), filed on March 25, 2005, and the amendment filed on January 31, 2005, has been entered. Examiner acknowledges that **claims 1-3, 6, 8-11, 20 and 23** have been amended, and **claim 24** has been added. Subsequently, **claims 1-3, 5, 6, 8-11, 14 and 20-24** are under consideration.
2. In the Office Action dated November 30, 2004, the Examiner indicated that **claim 14** would be allowable if rewritten in independent form including ALL the limitations of the base claim and any intervening claims. Merely incorporating only a portion of **claim 14** into a different independent claim than the one it originally depended from (claim 20) *does not* put newly presented **claim 24** into condition for allowance since the entire combination of claim elements of **claims 1 and 14** were not incorporated into **claim 24** as well.
3. In addition, the indication of allowable subject in **claim 14**, as stated in Office action, mail date November 30, 2004, has been withdrawn in view of new grounds of rejection as set forth in this Office action.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 1-3, 5, 6, 8 and 20-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gresser et al. (US 6,241,771 B1) in view of Jammet et al. (US 5,941,882).

Regarding **claim 1**, Gresser et al. discloses a screw **20** for medical purposes having a screw body made of biodegradable material (column 3, lines 65-67 and column 4). The device of Gresser et al. is an interference screw, since that shown in Figures 2A-2C is a screw and the term *interference* is defined as "the act or an instance of hindering, obstructing, or impeding; something that hinders, obstructs, or impedes," according to *The American Heritage® Dictionary of the English Language, Third Edition*.

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Moreover, the device of Gresser et al. anchors a transplant in a bone. Further, Gresser et al. discloses a device having a head portion having a facial end face, a shaft portion extending from the head portion from an end opposite to the facial end face along an axial direction of the screw body, a threading (such as **21**) provided on an outer side of the shaft portion (column 4, lines 34-43), as shown in Figures 2A-2C; at least one axially extending groove **26** cut into an outer side of the screw body, as seen in Figures 2A and 2C; the at least one groove extending along the head portion and an entire length of the shaft portion, as seen in Figures 2A-2C; at least one recess **23** provided in the facial end face of the head portion; a tool (necessary – as disclosed in column 4, lines 34-42). Thus, it would have a projection corresponding to the recess in the facial end face of the head portion of the screw; the projection can be introduced into the recess for centering the tool on the screw, given the structure.

Gresser et al. teaches an apparatus comprising all limitations recited in **claim 1**, but does not expressly recite the specifics of the drive tool. At the time of the invention was made, a drive tool with a length that corresponds to the length of the groove into which it is designed to engage was known. Therefore, it would be obvious to one with ordinary skill in the art to have the drive element **110** with lugs **150** that have a length to substantially correspond to the length of the grooves **118** which the lugs are to engage, such as taught by Jammet et al., as shown in Figures 5, 6 and 8. Moreover, Applicant has not asserted that this specific configuration of the drive tool recited provides a particular advantage, solves a stated problem or serves a purpose different from that of any other drive tool that would engage an interference screw, thus the use of drive tool

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with a length to corresponds to the length of the groove into which it engages lacks criticality in its utilization and design. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a drive tool that the length did not substantially correspond to the groove length, such as one that was slightly shorter, because as long as the drive tool was the appropriate size to fit around the screw and produce enough torque to screw in and/or remove the screw from its intended location, the drive tool would fully capable of inserting/removing the screw and functioning as a driver. Therefore, it would have been obvious to modify the apparatus of Gresser et al. by modifying the drive tool to have lugs with the same length as the grooves, as taught by Jammet et al., because it is well known in the art to have the length of the drive tool to correspond to the grooves into which it is meant to engage in order to more accurately and efficiently screw the interference screw into/out of place.

Regarding **claim 2**, Gresser et al. as modified by Jammet et al. discloses that as applied to **claim 1**, and it is within the scope of the invention and would further be necessary and obvious to one with ordinary skill in the art to assure the depth of the at least one axially extending groove that are such that the drive element of the driving tool lies within the at least one axially extending groove and does not extend beyond an outer periphery of the screw body, for proper insertion given spatial requirements.

Regarding **claim 3**, Gresser et al. as modified by Jammet et al. discloses that as applied to **claim 1**, and it is within the scope of the invention and would further be necessary and obvious to one with ordinary skill in the art to assure a depth of the at least one axially extending groove that are such that the drive element of the driving tool

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is housed within the groove without extending radially beyond the threading of the shaft portion, for proper insertion given spatial requirements.

Regarding **claim 5**, Gresser et al. discloses that as applied to **claim 1**, as well as, a recess **23** that is configured as a channel completely passing through the screw body.

Regarding **claim 6**, Gresser et al. discloses that as applied to **claim 1**, as well as, the at least one axially extending groove **26** comprises at least three axially extending grooves that are provided to be distributed uniformly about a circumference of the screw body, as seen in Figures 2A-2C.

Regarding **claim 8**, Gresser et al. discloses that as applied to **claim 1**, as well as, the at least one axially extending groove that is open axially at the facial end face end of the head portion, as seen in Figures 2A-2C.

Regarding **claim 20**, Gresser et al. discloses a screw **20** having an end face; a shaft extending from the head from an end opposite to the end face along an axial direction perpendicular to the head portion; a threading (such as **21**) provided on an outer surface of the shaft; and at least one axially extending groove **26** cut into and extending along an outer side of the head and an entire length of the shaft, as seen in Figures 5 and 6; and a shaft that tapers from the head portion to the end opposite to the end face. The at least one groove is capable of being provided for inserting of the at least one axially extending drive element of the drive tool therein.

Gresser et al. teaches an apparatus comprising all limitations recited in **claim 20**, but does not expressly recite the specifics of the drive tool. At the time of the invention

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was made, a drive tool with a length that corresponds to the length of the groove into which it is designed to engage was known. Therefore, it would be obvious to one with ordinary skill in the art to have the drive element **110** with lugs **150** that have a length to substantially correspond to the length of the grooves **118** which the lugs are to engage, such as taught by Jammet et al., as shown in Figures 5, 6 and 8. Moreover, Applicant has not asserted that this specific configuration of the drive tool recited provides a particular advantage, solves a stated problem or serves a purpose different from that of any other drive tool that would engage an interference screw, thus the use of drive tool with a length to corresponds to the length of the groove into which it engages lacks criticality in its utilization and design. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a drive tool that the length did not substantially correspond to the groove length, such as one that was slightly shorter, because as long as the drive tool was the appropriate size to fit around the screw and produce enough torque to screw in and/or remove the screw from its intended location, the drive tool would fully capable of inserting/removing the screw and functioning as a driver. Therefore, it would have been obvious to modify the apparatus of Gresser et al. by modifying the drive tool to have lugs with the same length as the grooves, as taught by Jammet et al., because it is well known in the art to have the length of the drive tool to correspond to the grooves into which it is meant to engage in order to more accurately and efficiently screw the interference screw into/out of place.

Regarding **claim 21**, Gresser et al. discloses that as applied to **claim 20**, as well as at least three grooves, as seen in Figures 2A-2C.

Regarding **claim 22**, Gresser et al. discloses that as applied to claim 21, as well as a head that has at least one recess **23** centered in the end face for receiving a projection on a drive element of the driving tool to center the drive element about the end face.

8. **Claims 14 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gresser et al. (US 6,241,771 B1) in view of Jammet et al. (US 5,941,882), as applied to **claims 1-3, 5, 6, 8 and 20-22** above, and further in view of Stone et al. (WO 99/44533). Gresser et al. as modified by Jammet et al. discloses an apparatus comprising all the limitations recited in **claims 14 and 24**, with the exception of the transplant being either a tendon or a ligament. However, the use of an interference screw to anchor a transplanted tendon or ligament in a bone was known at the time the invention was made. Specifically, Stone et al. teaches transplanting a ligament and then affixing the ligament with an interference screw (page 24, lines 23-27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Gresser et al. by modifying the interference screw to anchor a transplanted ligament because it is well known in the art, as taught by Stone et al., to use an interference screw in order to anchor a transplanted ligament.

Allowable Subject Matter

9. **Claims 9-11 and 23** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


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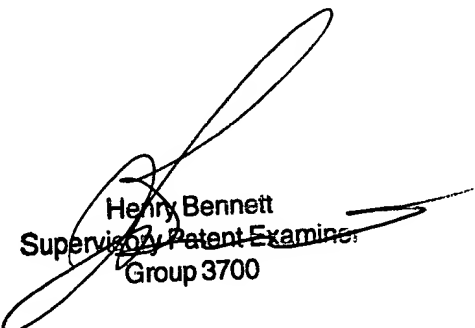
Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR 
June 13, 2005


Henry Bennett
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